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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/384,650 08/27/99 MICHAEL J D-1079-DIV

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PM82/0719

EXAMINER

BUTLER, M

ART UNIT

PAPER NUMBER

3651

DATE MAILED: 07/19/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/384,650

Applicant(s)

Michael et al.

Examiner

Michael E. Butler

Group Art Unit

3651



☒ Responsive to communication(s) filed on May 8, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 40-62 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 40-62 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 40-60 are rejected under 35 U. S. C. 112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention as in paper number 6. The applicant has conjoined elements using 'or' creating vague and indefinite claims (claim 40L 6; claim 42 L 1; cl 52 L 13; cl 53 L 18). The applicant should restructure the elements using a Markush grouping if coverage encompassing alternative elements is sought in the claims, "at least one of" if broad coverage is sought, or conjoin the elements with "and" for narrow coverage. These claims have been otherwise examined on the merits presuming the use of a Boolean "OR".

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

4. Claims 40, 42, 43, and 46-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Higham et al. '366 as in paper number 6. Higham et al '366 discloses: (Re: cl 40, 52, 53)

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moving the dispenser module from a position within the enclosure to a position outside the enclosure (col. 18 L 43-44); adding or removing at least one medical item from the holder while outside the enclosure (col. 18 L 45-47); moving the dispenser from outside the enclosure to within the enclosure such that the holder is within the enclosure (col. 22 L 10-15); (Re: cl 42) manually adding or removing at least one medical item from the holder (col. 18 L 43-45); (Re: cl 43) moving the dispenser out of the enclosure so as to make it manually accessible (col. 18 L 43-44); (Re: cl 46,57) reading indicia on a reference surface (col. 5 L 3-18); (Re: cl 47,58) moving the cover to the up position prior to moving the cover to the down position (col. 23 L 30-56).

The applicant points out an apparatus structural limitation unutilized by any method limitation in claims in attempting to distinguish the claimed invention from the prior art. A structural limitation within a method claim needs a functional relationship to the method limitations to be afforded patentable weight. "The dichotomy between process and product classes of invention has also been recognized and noted". Ex parte Lyell, 17 USPQ2d 1548,1552 (BdPatApp&Int, 1990) in the following discussion "A method or process... is an act or a series of acts and from the standpoint of patentability must distinguish over the prior art in terms of steps, whereas a claim drawn to apparatus must distinguish in terms of structure. The Patent Act of 1952 did not abolish the then existing different classes of invention. It reaffirmed the same by Section 101 of USC 35". Ex parte Lyell at 1552 citing Ex Parte Forsyth, 151 USPQ 55, 56 (Bd. of Appeals 1965); see also MPEP 2114 for the analogous rule on the unavailability of functional limitation solely as the distinction in apparatus claims from prior art.

5. Claims 40, 42, 43, and 46-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Kraft et al.. Kraft et al. discloses: (Re: cl 40, 52, 53) moving the dispenser module from a position within the enclosure to a position outside the enclosure (col. 5 L15-20); adding or

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removing at least one medical item from the holder while outside the enclosure (col.13 L45-56); moving the dispenser from outside the enclosure to within the enclosure such that the holder is within the enclosure (col. 8 L 8-38); (Re: cl 42) manually adding or removing at least one medical item from the holder (col. 4 L 35-50); (Re: cl 43) moving the dispenser out of the enclosure so as to make it manually accessible (col. 13 L 38-57); (Re: cl 46,57) reading indicia on a reference surface (col. 9 L 1-28; col. 7 L 59-65); (Re: cl 47, 58) moving the cover to the up position prior to moving the cover to the down position (col. 12 L 58-col. 13 L3).

6. Claims 40, 42, 43, 49, 60, 50, 51, and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Blechle as in paper number 6. Blechle discloses: (Re: cl 40, 52, 53) moving the dispenser module from a position within the enclosure to a position outside the enclosure (col. 3 L 52-col. 4 L 2); adding or removing at least one medical item from the holder while outside the enclosure (col. 2 L 22-24 ; col. 3 L 52-col. 4 L 2); moving the dispenser from outside the enclosure to within the enclosure such that the holder is within the enclosure (col. 3 L 52-col. 4 L 2); (Re: cl 42) manually adding or removing at least one medical item from the holder (col. 3 L 52-col. 4 L 2); (Re: cl 42) moving the dispenser out of the enclosure so as to make it manually accessible (col. 3 L 52-col. 4 L 2); moving the dispenser module within the enclosure and adjacent to the path;(RE: cl 50) providing the holder with a plurality of items arranged in a stack (col. 7 L 46-col. 8 L 13); engaging a follower in engagement with the stack (col. 7 L 46-col. 8 L 13); (Re: cl 51) adding a plurality of medical items to the holder in side by side relation to a stack (col. 5 L 61-68); (Re: cl 61) providing an enclosure with a delivery area accessible from outside the enclosure providing a first dispenser module within the enclosure, wherein dispenser module includes a plurality of medical items and is selectively operative to dispense first medical items therefrom;providing a second dispenser module in the enclosure in supporting connection with

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the enclosure through a second support, wherein second and first supports are interchangeably engageable to support the first or second dispenser modules, and second dispenser includes a plurality of second medical items selectively operative to dispense the second medical items therefrom, wherein second medical items are dispensed from the second dispenser in the enclosure (col. 2 L 13-31); dispensing at least one of a first or second medical item to the delivery area (col. 7 L 46-col. 8 L 13).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 40-43, 46-47, 49, 52-54, 57-58, 60, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Higham et al. '366 as in paper number 6. Higham et al. '366 the elements previously disclosed and further discloses: (Re: cl 41, 52-53) opening the door prior to moving the holder outside the enclosure (col. 18 L 45-47); (Re: cl 49, 60, 62) dispensing a first medical item including a supporting card from the module (col.18 L 1-15; Fig. 3, # 52); dispensing a second medical item including a cylindrical holding container from the dispenser module(Fig. 21 , #260). Higham et al. '366 does not disclose: closing the door after moving the holder inside the enclosure; that the cylindrical holding container contains a liquid. Higham et al. '366 does disclose a closed door (col. 18 L 43-47; Fig. 1, # 16). It would have been obvious to close the door after moving the holder inside the enclosure because the door was closed before the procedure commenced, the door may only be closed after the holder is inside the closure.

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Therefore it would have been obvious to close the door after the holder is within the enclosure because closing the door limits access, protects the holder, and facilitates portability of the dispenser as taught by Higham et al. '366. The examiner takes official notice that the use of cylindrical holding containers is well known in the medical products art. It would have been obvious to use a cylindrical holding container in the dispensing of medical products because cylindrical holding containers are sturdy and permit easy access to the contents.

9. Claims 40-43, 44, 46-49, 52-60, 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Higham et al. '366 in view of Kraft et al. as in paper number 6. Higham et al. '366 discloses the elements previously discussed. Higham et al. '366 does not disclose: engaging a helix within the holder a rotating mechanism; engaging a holder guide wherein the first portion of the holder guide is extended in an inside are within the helix and a second portion outside the helix; placing a medical item in engagement with each of a pair of helixes; extending a limiting member within the inside of the helix, wherein the limiting member prevents medical items from passing through the inside of the helix.

Kraft et al. discloses: (Re: cl 44,55) engaging a helix within the holder a rotating mechanism; engaging a holder guide wherein the first portion of the holder guide is extended in an inside are within the helix and a second portion outside the helix (col. 8 L 25-67); (Re: cl 45,56) placing a medical item in engagement with each of a pair of helixes (col. 5 L 21-37; col. 7 L 26-38; col. 8 L 25-67); (Re: cl 48,59) extending a limiting member within the inside of the helix, wherein the limiting member prevents medical items from passing through the inside of the helix (col. 8 L 25-67). It would have been obvious for Higham et al. '366 to engage such a helix because such action facilitates dispensing of bulk medications as taught by Kraft et al.. It would have been obvious for Higham et al. '366 to place a medical item in engagement with

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each of a pair of helixes because placing the medical item in engagement is a necessary precursor to the dispensing of bulk medical items as taught by Kraft et al.. It would have been obvious for Higham et al. '366 to extend a limiting member within the inside of the helix because such a limiting member prevents extraneous dispensing of medicine as taught by Kraft et al..

10. Claims 40-43, 44, 45-49, 52-60, 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kraft et al.. in view of Pitel et al.. Kraft et al.. discloses the elements previously discussed and further discloses placing a dispensate medical item in engagement with each of a helix. Kraft et al. does not disclose placing a dispensate item in contact with a pair of helixes. Pitel et al. discloses placing a dispensate item in contact with a pair of helixes (abstract). It would have been obvious for Kraft et al. to place the dispensate in contact with a second helix because dual helixes are more reliable and more flexible in the size and width of dispensed products than are single helix dispensers as taught by Pitel et al..

11. Claims 40, 52, 43, 45, 53 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pitel et al.. Pitel et al. discloses: (Re: cl 40, 52, 53) moving the dispenser module from a position within the enclosure to a position outside the enclosure (col. 7 L 27-415 L15-20); adding or removing at least one item from the holder while outside the enclosure (col.7 L 27-41); moving the dispenser from outside the enclosure to within the enclosure such that the holder is within the enclosure (col.7 L 27-41); (Re: cl 42) manually adding or removing at least one item from the holder (col. 7 L 27-41); (Re: cl 43) moving the dispenser out of the enclosure so as to make it manually accessible (col. 7 L 27-41); placing a dispensate item in contact with a pair of helixes (abstract). Pitel et al. does not disclose the item removed and placed within the dispenser and in contact with the dual helixes is a medical item. The examiner takes official notice that the dispensing of medicaments such as aspirin and antacids is well known in the

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vending arts. It would have been obvious for Pitel et al. to place a medicament within the helical dispensing tray because aspirin is a saleable and vendible product and its distribution is a service to consumers.

12. Claims 40, 42, 43, 44, 46, 48-50, 51, 55, 59-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blechle in view of Kraft et al. as in paper number 6. Blechle discloses the elements previously discussed. Blechle does not disclose: engaging a helix within the holder a rotating mechanism; engaging a holder guide wherein the first portion of the holder guide is extended in an inside are within the helix and a second portion outside the helix; placing a medical item in engagement with each of a pair of helixes; extending a limiting member within the inside of the helix, wherein the limiting member prevents medical items from passing through the inside of the helix.

Kraft et al. discloses: (Re: cl 44,55) engaging a helix within the holder a rotating mechanism; engaging a holder guide wherein the first portion of the holder guide is extended in an inside are within the helix and a second portion outside the helix (col. 8 L 25-67); (Re: cl 45,56) placing a medical item in engagement with each of a pair of helixes (col. 5 L 21-37; col. 7 L 26-38; col. 8 L 25-67); (Re: cl 48,59) extending a limiting member within the inside of the helix, wherein the limiting member prevents medical items from passing through the inside of the helix (col. 8 L 25-67). It would have been obvious for Blechle to engage such a helix because such action facilitates dispensing of bulk medications as taught by Kraft et al.. It would have been obvious for Blechle to place a medical item in engagement with each of a pair of helixes because placing the medical item in engagement is a necessary precursor to the dispensing of bulk medical items as taught by Kraft et al.. It would have been obvious for

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Blechle to extend a limiting member within the inside of the helix because such a limiting member prevents extraneous dispensing of medicine as taught by Kraft et al..

13. Claims 40-43, 46-47, 49, 50-54, 57-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Higham et al. '366 in view of Blechle as in paper number 6. Higham et al. '366 the elements previously disclosed and further discloses: (Re: cl 41, 52-53) opening the door prior to moving the holder outside the enclosure (col. 18 L 45-47); (Re: cl 49, 60, 62) dispensing a first medical item including a supporting card from the module (col.18 L 1-15; Fig. 3, # 52); dispensing a second medical item including a cylindrical holding container from the dispenser module(Fig. 21 , #260). Higham et al. '366 does not disclose: closing the door after moving the holder inside the enclosure; that the cylindrical holding container contains a liquid ; providing the holder with a plurality of items arranged in a stack ; engaging a follower in engagement with the stack adding a plurality of medical items to the holder in side by side relation to a stack . Higham et al. '366 does disclose a closed door (col. 18 L 43-47; Fig. 1, # 16). It would have been obvious to close the door after moving the holder inside the enclosure because the door was closed before the procedure commenced, the door may only be closed after the holder is inside the closure. Therefore it would have been obvious to close the door after the holder is within the enclosure because closing the door limits access, protects the holder, and facilitates portability of the dispenser as taught by Higham et al. '366. Blechle discloses the use of cylindrical holding containers for liquids (col. 8 L 18-36); providing the holder with a plurality of items arranged in a stack (col. 7 L 46-col. 8 L 13); engaging a follower in engagement with the stack (col. 7 L 46-col. 8 L 13); (Re: cl 51) adding a plurality of medical items to the holder in side by side relation to a stack (col. 5 L 61-68). It would have been obvious to use a cylindrical holding container in the dispensing of medical products because cylindrical holding containers are sturdy and permit

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easy access to the contents as taught by Blechle. It would have been obvious to a holder with a plurality of items arranged in a stack because such a dispensing arrangement facilitates repetitive dispensing of common sized items as taught by Blechle. It would have been obvious to engage a follower with the stack because such an engagement permits medication to be dispensed in a two phase approach facilitating dispensing in a secure way. It would have been obvious to place a plurality of medical items in side by side relation to the stack because such an arrangement facilitates the storing and dispensing of medications of varying sizes as taught by Blechle.

Conclusion

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Exmr. Michael E. Butler whose telephone number is (703) 308-8344.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Ellis, can be reached on (703) 308-2560. The fax number for the Group is (703) 305-7687.



Michael E. Butler

Examiner

MICHAEL E. BUTLER
PATENT EXAMINER